



## Bay Area Dioxins Project

# Permit Requirements for Installing Autoclaves at Acute Care Hospitals

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JCAHO Environment of Care  
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## About This Summary

California law—the Medical Waste Management Act—defines specific requirements for handling and treating medical waste. This summary includes all requirements enforced by the California Department of Health Services. In many cities and counties, a local government agency enforces the Medical Waste Management Act. Local Enforcement Agency requirements and fees may differ slightly from the summary below.

## What Permits Are Needed?

- Medical Waste Treatment permit from the local California Medical Waste Management Act Enforcement Agency (same agency that administers medical waste generator requirements)
- Office of Statewide Health and Planning Development (OSHPD) plan review or a building permit from your city or county (see the Frequently Asked Questions list for information on OSHPD review)
- (Sometimes) A Conditional use permit may be required by the local zoning code—contact your local planning department for more information
- (Sometimes) A new or modified sewer discharge permit—contact your local sewer agency for more information

*Note: on-site treatment of medical waste by steam sterilization is exempt from the California Environmental Quality Act, so no EIR or Negative Declaration should be needed unless autoclave installation is part of a larger project.*

## Medical Waste Management Requirements Change Little With Autoclave Installation

Requirements for Acute Care Hospitals	Requirements for Acute Care Hospitals with Autoclaves
Registration	Registration and permit for treatment.
Prepare Medical Waste Management Plan	Same. Include treatment activities in Medical Waste Management Plan—simply need to list type of treatment, treatment capacity, and a reference to treatment facility documents.
If hospital makes significant physical or operational changes, must update Medical Waste Management Plan	Same, unless the project involves physical changes to the autoclave facility. If changes affect medical waste treatment, must update treatment facility-related documents and must notify Enforcement Agency at least 30 days prior to construction; may need to update permit before using modified facility.
Can store waste for up to 7 days above 0°C or up to 90 days at or below 0°C	Same
Inspections at least annually	Same
Civil and criminal penalties for violations	Same
Registration may be suspended, amended or revoked for violations	Same (treatment permit may separately be suspended, amended, or revoked)
Properly manage medical waste	Same
Keep treatment records for 3 years	Same (but a few more records to keep)
No routine reporting requirements	Same
No renewal requirement	Renew permit every 5 years.
Pay annual fee set by Enforcement Agency (about \$500 to \$1,500 per year; local fees may be higher)	Pay larger annual fee (state fees are \$800 to \$2,500 per year; local fees may be higher).

\*Assumes that the acute care hospital is a large quantity generator.

## Steps for Getting (or Modifying) a Medical Waste Treatment Permit

1. Apply. Apply for a permit from the hospital's Enforcement Agency (see attached checklist).
2. Work with Enforcement Agency. Enforcement agency reviews application, works with hospital to answer questions.
3. Construction/Installation. Obtain written approval from enforcement agency before beginning construction.
4. Permit Issued. When construction is complete, submit a letter from the hospital and a California-registered P.E. stating that the facility has been constructed (or modified) in compliance with the permit. The Enforcement agency will inspect the facility and may charge a small processing fee (typically less than \$150) prior to issuing the permit, which may contain conditions or prohibitions to ensure protection of public health.

## Operation Requirements for Autoclaves at Acute Care Hospitals are Straightforward

State regulations require that treatment facilities be properly operated and maintained, which is defined to include "effective performance, adequate funding, adequate operator staffing and training, and adequate laboratory and process controls, including appropriate quality assurance procedures."

- ❑ Standard Operating Procedures (SOPs). Write down and follow SOPs (these are often provided by manufacturers). The primary operating requirement is that the temperature must get to at least 121°C (250°F) for at least 30 minutes.
- ❑ Monitor treatment operations. For every load, check the autoclave's written record of the temperature and pressure (or check the autoclave thermometer and heat sensitive tape on each bag) to ensure it indicates treatment is adequate. At least monthly, test the efficacy of the unit under standard operating conditions by placing *bacillus stearothermophilus* (or another indicator approved by DHS) in the center of a load. For all operations monitoring, record date, exact place, time, results, and person's name. For bacterial indicator samples, record analysis date, analyzer name, and analytical method.
- ❑ Calibrate monitoring thermometers annually.
- ❑ Keep Records. Keep permit application records (along with any supplemental information submitted) for the life of the permit. Keep any permit-related reports and all operations and monitoring records (like records of SOPs, load thermometer readings, annual thermometer calibration, monthly biological indicator test, and any other calibration, sampling, and monitoring) for at least 3 years.
- ❑ No routine reporting. Enforcement Agencies can require responses to requests for information relevant to the medical waste treatment facilities within 30 days.
- ❑ Noncompliance must be reported and corrected promptly. If it endangers health, safety, or the environment, must be reported orally with 24 hours with follow up written report within 5 days. Otherwise, must be reported in next monitoring report.

## Medical Waste Treatment Permit Application Checklist for Installing an Autoclave at an Acute Care Hospital

***This is a summary of California Department of Health Services Requirements. Where a local agency serves as the Enforcement Agency, requirements may differ slightly and fees may be somewhat higher.***

- ❑ Obtain forms—Contact your local medical waste management act enforcement agency to obtain the appropriate forms.
- ❑ Basic facts—Hospital name, address, telephone number, type of business entity (e.g., general acute care hospital); business activity (usually this is part of the permit application form).
- ❑ Facility location information—Facility name, mailing address, physical location, map (like a USGS topographic map) extending one mile beyond the property boundary in all directions indicating land uses (e.g., residential commercial, recreational, schools).
- ❑ Treatment information—Type of treatment unit (e.g., autoclave), capacity, characterization of waste (e.g., biohazardous, sharps), estimated average monthly quantity to be treated, disposal plans for treated waste (e.g., landfill). (This should be an addition to the hospital's *Medical Waste Management Plan*.)
- ❑ Facility details—Scale drawing and general description of the facility showing location of all treatment and storage areas.
- ❑ General Operations Plan—Plan must have a schedule for monitoring equipment inspection and calibration, disinfection procedures, location and type of safety and emergency equipment and security devices, security procedures, and any other operational or structural measures that prevent hazards or assist with response to accidents. (This should be an addition to the hospital's *Medical Waste Management Plan*.)
- ❑ Emergency Action Plan—Modify hospital's *Medical Waste Management Plan* to address autoclave equipment breakdowns, natural disasters, or any other occurrences that might interfere with on-site autoclaving of medical waste.
- ❑ Training Program outline—Cover both introductory and continuing employee operations and maintenance training and include a brief description of how training will be designed to meet actual job tasks. (This should be an addition to the hospital's *Medical Waste Management Plan*.)
- ❑ Closure Plan—Include a written estimate of closure costs at the most expensive time in the facility's operating life.
- ❑ Monitoring Plans—Schedule and standard operating procedures (SOPs) for monitoring operation temperature and the attainment of adequate sterilization conditions for each load (usually these two items are fulfilled by temperature/pressure monitoring equipment that is an integral part of the autoclave) and monthly bacteriological samples. If any other monitoring equipment is planned, schedule for installation and written SOPs for monitoring equipment use, maintenance, and testing. (This should be an addition to the hospital's *Medical Waste Management Plan*.)
- ❑ Evidence of ability to comply—Describe all environmental or medical waste management violations for last 3 years at any California medical waste management facility owned/operated by applicant.
- ❑ Signature—Signed by both owner and operator (if not the same)—corporate officer, general partner, public agency principal executive officer or ranking elected official (usually a signature block is part of the permit application form).
- ❑ No application fee